UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/674,857	11/07/00	ARMOUR	K 620-117

HM22/0628

NIXON & VANDERHYE
8TH FLOOR
1100 NORTH GLEBE ROAD
ARLINGTON VA 22201-4714

EXAMINER	
HUYNH, P	
ART UNIT	**PAPER NUMBER**
1644	9

DATE MAILED: 06/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/674,857	ARMOUR ET AL.	
	Examiner	Art Unit	
	" Neon" Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Preliminary amendments, filed 11/7/00, are acknowledged.
Claims 3, 7, 9, 10, 12, 13, 14, 16, 17 and 21 have been amended.
Claims 4-6, 8, 18, 20, 23 and 27-30 have been not been entered because the specified phrases were found in said claims.
Claims 1-34 are pending.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this Action, to elect a single invention to which the claims must be restricted:

I. Claims 1-19 and 33, drawn to a binding molecule comprising a binding domain and an effector domain wherein the binding domain is the binding site of an antibody and the effector domain is homologous to all or part of a constant domain of a human immunoglobulin heavy chain selected from IgG1, IgG2, and IgG4.

II. Claims 1-19 and 33, drawn to a binding molecule comprising a binding domain and an effector domain wherein the binding domain is the binding site of an enzyme and the effector domain is homologous to all or part of a constant domain of a human immunoglobulin heavy chain selected from IgG1, IgG2, and IgG4.

III. Claims 1-19 and 33, drawn to a binding molecule comprising a binding domain and an effector domain wherein the binding domain is the binding site of a hormone and the effector domain is homologous to all or part of a constant domain of a human immunoglobulin heavy chain selected from IgG1, IgG2, and IgG4.

IV. Claims 1-19 and 33, drawn to a binding molecule comprising a binding domain and an effector domain wherein the binding domain is the binding site of a receptor and the effector domain is homologous to all or part of a constant domain of a human immunoglobulin heavy chain selected from IgG1, IgG2, and IgG4.

V. Claims 1-19 and 33, drawn to a binding molecule comprising a binding domain and an effector domain wherein the binding domain is the binding site of a cytokine and the effector domain is homologous to all or part of a constant domain of a human immunoglobulin heavy chain selected from IgG1, IgG2, and IgG4.

VI. Claims 1-19 and 33, drawn to a binding molecule comprising a binding domain and an effector domain wherein the binding domain is the binding site of an antigen and the effector domain is homologous to all or part of a constant domain of a human immunoglobulin heavy chain selected from IgG1, IgG2, and IgG4.

VII. Claims 20-25 and 33, drawn to an isolated nucleic acid comprising a nucleotide sequence encoding the effector domain of the binding molecule, vector, host cell, a method of producing said binding molecule and a pharmaceutical preparation.

VIII. Claims 26-32, drawn to a method of using a binding molecule of RhD antigen of red blood cell for the treatment of a patient with a disorder.

IX. Claims 26-32, drawn to a method of using a binding molecule of an HPA alloantigen of platelets for the treatment of a patient with a disorder.

X. Claims 26-32, drawn to a method of using a binding molecule of a T cell receptor for the treatment of a patient with a disorder.

XI. Claims 26-32, drawn to a method of using a binding molecule of an integrin for the treatment of a patient with a disorder.

XII. Claims 26-32, drawn to a method of using a binding molecule of a lutheran for the treatment of a patient with a disorder.

XIII. Claims 26-32, drawn to a method of using a binding molecule of a platelet glycoprotein VI and Ia/IIa for the treatment of a patient with a disorder.

XIV. Claims 26-33, drawn to a method of using a nucleic acid coding for binding molecule of RhD antigen of red blood cell and a pharmaceutical preparation for the treatment of a patient with a disorder.

XV. Claims 26-32, drawn to a method of using a nucleic acid coding for binding molecule of an HPA alloantigen and a pharmaceutical preparation for the treatment of a patient with a disorder.

XVI. Claims 26-32, drawn to a method of using a nucleic acid coding for binding molecule of a neutrophil antigen and a pharmaceutical preparation for the treatment of a patient with a disorder.

XVII. Claims 26-32, drawn to a method of using a nucleic acid coding for binding molecule of a T-cell receptor and a pharmaceutical preparation for the treatment of a patient with a disorder.

XVIII. Claims 26-32, drawn to a method of using a nucleic acid coding for binding molecule of an integrin and a pharmaceutical preparation for the treatment of a patient with a disorder.

XIX. Claims 26-32, drawn to a method of using a nucleic acid coding for binding molecule of a lutheran and a pharmaceutical preparation for the treatment of a patient with a disorder.

XX. Claims 26-32, drawn to a method of using a nucleic acid coding for binding molecule of platelet glycoprotein Ia/IIa and a pharmaceutical preparation for the treatment of a patient with a disorder.

XXI. Claim 34, drawn to oligonucleotides.

The Invention of Groups I-XXI was to have no special technical feature that defined the contribution over the prior art of Cole et al (Immunology 159: 3613-3621; PTO 1449).

Cole et al teach a binding molecule which is a recombinant polypeptide comprising a binding domain of a receptor to T cell and an effector domain having an amino acid sequence substantially homologous to all or part of a constant domain of a human heavy chain. The said effector domain is capable of specifically binding to FcγIIb, and is derived from two or more

human immunoglobulin heavy chain CH2 domains from IgG2, as recited in claims 1-4 and 17 (See page 3614, Materials and Methods, page 3617-3619, in particular).

Since Applicants' Inventions do not contribute a special technical feature when viewed over the prior art, Groups I-XXI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept and therefore lack unity of invention.

5. This application contains claims directed to the following patentably distinct species of binding molecule as recited in claims 18-19 and distinct disorder as recited in claim 31.
These species of binding molecules are distinct because the binding molecules differ with respect to their structures, physiochemical properties, and their site of action.
These disorders are distinct because these diseases differ with respect to their etiology and therapeutic endpoints.

6. Applicants are required under 35 U.S.C. § 121 to elect a single disclosed species of binding molecule as recited in claims 18-19 and a single disclosed species of disorder as recited in claim 31 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 20, 26, and 31 are generic.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.

9. Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

12. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Patrick J. Nolan

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
June 28, 2001

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600